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August 30, 2023

Honorable Michael A. Shipp, U.S.D.J.
United States District Court
Clarkson S. Fisher Building & US Courthouse
402 East State Street
Trenton, NJ 08608

Honorable Rukhsanah L. Singh, U.S.M.J
United States District Court
Clarkson S. Fisher Building & US Courthouse
402 East State Street
Trenton, NJ 08608

***Re: Johnson & Johnson Talcum Powder Products, Marketing, Sales
Practices and Products Liability Litigation***
Case No.: 3:16-md-02738-MAS-RLS

Dear Judge Shipp and Judge Singh:

The Plaintiffs' Steering Committee (PSC) submits the following in response to statements in the Johnson & Johnson Defendants' letter of August 23, 2023 that we believe do not comport with the scientific and procedural facts.

The PSC submitted to the Court a separate Stage Three case management order for the purpose of making clear that any newly filed *Daubert* motions should be related to case-specific and general expert opinions *not* previously addressed by the Court. In August 2021, at the time the first Stage Three case management order was entered, the parties were proceeding toward a bellwether trial with the clear understanding that Judge Wolfson's April 27, 2020 order had addressed *Daubert* challenges involving general causation expert opinions of the parties' regarding epidemiology, gynecologic oncology, toxicology, cell biology, and asbestos and talc

fiber testing. It was clear in that context that a *Daubert* “redo” was not on the table for previously addressed expert opinions. Judge Wolfson’s 141-page *Daubert* order was the law of the case. The same should be true today. The Johnson & Johnson Defendants should not be allowed to re-litigate previously decided issues on the basis that time has passed, a **two-year** delay caused by Defendants’ two bad faith bankruptcy filings.

Furthermore, the science in support of causation has not changed in favor of Defendants. Rather, the science in support of a causal connection between the genital use of talcum powder and epithelial ovarian cancer continues to get stronger. Defendants focus on the 2019 O’Brien study,¹ a study that was submitted to the Court prior to its April 2020 *Daubert* decision.

Defendants argue that the O’Brien study is conclusive proof that the genital use of talcum powder does not cause ovarian cancer, permanently tilting the causation landscape in Johnson & Johnson’s favor. Nothing could be further from the truth. Defendants selectively report the O’Brien study authors’ conclusions and ignore significant study data and findings relevant to the women diagnosed with ovarian cancer represented in this litigation. While the overall relative risk for “ever use” versus “never use” of genital talcum powder was 1.08 (CI 0.99-1.17), there was a significantly elevated risk found in women with **patent (open) reproductive tracts** (RR 1.13; CI 1.01-1.26). In addition, a statistically significant increased risk was noted in **frequent users** (at least weekly). For more than five years, the PSC has made clear that general causation experts support cases involving women who were frequent users of talcum powder during periods in which they had open reproductive tracts, making these findings from O’Brien the most relevant, findings that Defendants omitted.

Moreover, the O’Brien study brought into focus the need for research on the issue of exposure, specifically frequent genital talcum powder use. Historically, systematic reviews of talcum powder use and ovarian cancer focused on “ever use,” a non-specific exposure which can obscure meaningful associations. In 2022, Drs.

¹ O’Brien et al., *Association of Powder Use in the Genital Area with Risk of Ovarian Cancer*. 323 JAMA 49 (2020); O’Brien et al., *Supplementary Online Content* (2020). The O’Brien investigators pooled data from the three (3) cohort studies: Nurse’s Health Study I and II (NHS), Women’s Health Initiative (WHI), and the Sisters’ Study. This study included 252,745 subjects **but** only 1,884 medically confirmed ovarian cancers.

Woolen, Lazar and Smith-Bindman² conducted a systematic review and meta-analysis of observational studies to estimate the association between frequent (at least 2 times per week) genital talcum powder use and ovarian cancer.³ This review reported that frequent talcum powder use was associated with a statistically significant **47% increased** risk of ovarian cancer (RR 1.47 (95% CI 1.31, 1.65, P<0.0001)).

Importantly, Health Canada conducted a systematic review of the evidence and weighed in on the issue of talcum powder usage and ovarian cancer. In December 2018, Health Canada preliminarily concluded that, “available human studies . . . indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer. Further, available data are indicative of a causal effect.”⁴

Over the course of 2019 and 2020, Johnson & Johnson submitted a 255-page review of the data and several countervailing expert reports to Health Canada. Its employees lobbied Health Canada on multiple occasions. Johnson & Johnson also made available to Health Canada via its website, www.thefactsabouttalc.com, the expert reports of both parties which were previously submitted to Judge Wolfson in this case.

After considering these materials, Health Canada published its final assessment in 2021, after the *Daubert* decision.⁵ Not only did Health Canada reaffirm that talc causes ovarian cancer, but it also specifically addressed – and rejected – the reasoning employed by J&J’s litigation experts:

“Overall, there is a high degree of consistency in the epidemiological studies across several decades conducted in different parts of the

² Dr. Rebecca Smith-Bindman serves as a general causation expert on behalf of Plaintiffs in the MDL.

³ Woolen, SA, et al., *Association Between the Frequent Use of Perineal Talcum Powder Products and Ovarian Cancer: a Systematic Review and Meta-analysis*. J Gen Intern Med (2022).

⁴ Health Canada, Draft Screening Assessment, Environment and Climate Change Canada, Dec. 2018, at 28 (emphasis added), available at <https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/screening-assessment-talc.html>.

⁵ Health Canada, Screening Assessment, Environmental and Climate Change Canada, April 2021.

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*world. Although there are uncertainties related to bias, **there is confidence in the robustness of the available database for use in characterizing ovarian cancer risk attributed to talc exposure. Furthermore, the available data are indicative of a causal relationship.***”⁶

Health Canada concluded that “the available human studies in the peer-reviewed literature indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer.”⁷

Lastly, contrary to Defendants’ assertion, the order proposed by the PSC does not require that new literature be ignored. In fact, the PSC’s proposed order contemplates general causation experts considering new material and being subject to limited depositions based on any new material. The consideration of new material, however, should not open the door to renewed motions or additional discovery of the *same* experts for the *same* opinions. Judge Wolfson has already painstakingly examined the experts’ analyses, processes, and techniques, ultimately ruling that Plaintiffs’ experts’ methodologies were sound and scientifically reliable. To the degree Defendants believe any new scientific references undermine existing experts’ opinions, these are matters that should be left to cross-examination at trial.

Thank you for your consideration. We look forward to discussing these and other matters during the upcoming status conference.

Respectfully submitted,

/s/ P. Leigh O'Dell

/s/ Michelle A. Parfitt

P. Leigh O'Dell

Michelle A. Parfitt

⁶ Health Canada, Screening Assessment, at 36 (emphasis added).

⁷ Id. at iii.

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cc: Hon. Joel Schneider, U.S.M.J. (ret.) (via email)
Susan Sharko, Esq. (via email)
All Counsel (via ECF)